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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/586,156 06/02/00 ARNOLD

L IN-0016-1

EXAMINER

HM22/0705

RICHARD ARON OSMAN
SCIENCE & TECHNOLOGY LAW GROUP
75 DENISE DRIVE
HILLSBOUROUGH CA 94010

LU.F

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

09/568,156

Applicant(s)

Arnold et al.,

Examiner

Frank Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jun 22, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on May 18, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

4. ☐ Applicant's reply has overcome the following rejection(s): _____
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
- Claim(s) allowed: _____
- Claim(s) objected to: 4-7
- Claim(s) rejected: 1-3 and 8-24
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other: _____

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ADVISORY ACTION

Response to Arguments

1. The purposed amendments filed on June 22, 2001 have been fully considered but will not be entered because they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issue for appeal (containing the rejections under 35 U.S.C. § 102 and 103).
2. In page 2, last paragraph bridging to page 3, first paragraph of applicant's remarks, applicant argued that "the structural requirements of our claims are neither met nor suggested by the cited Bates et al." because: (1) "there is no complementarity" in this reference "as expressly required by our claims"; and (2) "even with Bates' polyT/polyA homopolymers, the orientation of the polyT prob binding is parallel (not complementary) with the polyA of the duplex (see Fig. 2) and the polyA probe binding of the A30-A30-T30 triplex (p.3630) is antiparallel with the polyA-not with the polyT".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, applicant did not claim a product (probe-target complex) but a method. A polynucleotide probe to a polynucleotide target were separate products before they bound together. Claims such as claim 1 only required that single-stranded polynucleotide has complementarity (capable of complementing with) to one strand of a double stranded polynucleotide, claims did not have the limitations that the single stranded target was complementary to one strand of a double stranded probe or a single stranded probe was complementary to one strand of a double stranded target in the probe-target complex. Second,

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Bates et al., did not teach a A30-A30-T30 triplex but taught a A30-T30-A30 triplex (see page 3630, right column).

3. In page 3, last paragraph bridging to page 6, first paragraph of applicant's remarks, applicant argued that "Tyagi can not meet or suggest (and necessarily teaches directly away from) our method's requirement that the single stranded component (here, the target) have complementarity with one of the stranded of the double-stranded component (here, the probe)".

This arguments has been fully considered but it is not persuasive toward the withdrawal of the rejection because Tyagi *et al.*, do teach "the single stranded component (here, the target) have complementarity with one of the stranded of the double-stranded component (here, the probe)".

As shown in Figure 2 (304), at least one of nucleotides at double stranded region of the molecule beacon had complementarity (capable of complementing with) to one of bases of single stranded target. Furthermore, the loop region of the molecule beacon could be considered as a single strand region of one of the complementary strands of a partial double-stranded probe, which had complementarity (capable of complementing with) to single stranded target.

4. In page 3, last paragraph bridging to page 6, first paragraph of applicant's remarks, applicant argued that "nowhere described or suggested is the claimed solid phase hybridization assay involving triplex formation by hybridization between complementary target and probes".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because the motivation to combine cited reference is not based on a triplex formation as applicant suggested, but is dependent on a duplex formation.

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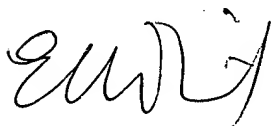
5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
July 1, 2001



Ethan Whisenant, Ph.D.
Primary Examiner (FSA)